

## 510(k) Summary<sup>1</sup>

DEC - 5 2006

(a) (1) **Submitter's name, address**

Bionostics, Inc.  
7 Jackson Road  
Devens, MA 01434

**Contact Person**

Randy Byrd  
Chief Technical Officer  
(978) 772-7070 x 272

**Date of preparation of this summary:** 8 November 2006

(2) **Device trade or proprietary name:** LeadCare II Lead Controls

**Device common or usual name or classification name:**

Clinical Toxicology Control Material

PRODUCT NOMENCLATURE	CLASSIFICATION NUMBER	CLASS	PANEL
Clinical Toxicology Control Material	862.3280 (DIF)	I	Toxicology

### I. Substantial Equivalence

ESA LeadCare II Lead Control is substantially equivalent in function, safety and efficacy to the Kaulson Laboratories Heavy Metal Control currently distributed with the LeadCare II test kits.

#### Comparison of Technological Characteristics with Predicate Device

Characteristic	New Device	Predicate Device
Name:	LeadCare II Lead Control	Kaulson Labs LeadCare Lead Control
510(k):	--	K830234
Description:	Aqueous solution containing bovine albumin, lead salts, preservatives and dye.	Lyophilized whole bovine blood with pre-measured water for dilution
Intended Use:	<b>LeadCare II Lead Controls</b> are intended for use as a quality control to monitor the precision of measurement and verify the performance of the ESA Biosciences LeadCare II System at two distinct levels within the measurement range.	<b>LeadCare Lead Controls</b> are intended for use as a quality control to monitor the precision of measurement and verify the performance of the ESA Biosciences LeadCare II System at two distinct levels within the measurement range.
Levels:	2	2
Analytes:	Lead	Lead

<sup>1</sup> This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

## **II. Description of the new device**

The ESA LeadCare II Control is customized for use on the ESA Biosciences LeadCare II Lead Analyzer and are used to verify the performance of the LeadCare II analyzers and sensors for the measurement of lead. The control solution is an aqueous solution containing bovine albumin, lead, buffers, preservative and dye in concentrations determined optimal for the LeadCare II system. The product is provided in two distinct levels, in screw capped, glass vials, each containing 2 mL of solution. One set of controls will be packaged with each LeadCare II test kit for use in quality control testing of the sensors, and verification of system performance.

LeadCare II Control provides a convenient method of performing periodic QC checks for laboratories selecting to measure liquid QC material as a part of their quality assurance program. The product is packaged in a glass bottle.

LeadCare II Control is a non-hazardous liquid control solution containing no human biological materials and requires no reconstitution prior to use.

### **(5) Intended use of the device**

**LeadCare II Lead Controls** are intended for use as a quality control to monitor the precision of measurement and verify the performance of the ESA Biosciences LeadCare II System at two distinct levels within the measurement range.

### **(b) (1) Summary of non-clinical tests submitted with the premarket notification for the device.**

Tests were conducted to verify specific performance requirements:

- a) Preservative Efficacy
- b) Closed bottle stability
- c) Stability after opening
- d) Comparison to predicate device
- e) Test precision and range

### **(b) (2) Summary of clinical tests submitted with the premarket notification for the device.**

N/A

### **(b) (3) Conclusions drawn from the clinical and non-clinical trials.**

Comparison of technological characteristics, formulation and intended use to predicate devices listed in this summary support the claim of substantial equivalence.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Randy Byrd  
Chief Technical Officer  
Bionostics, Inc.  
7 Jackson Road  
Devens, MA 01434

DEC - 5 2006

Re: k063398  
Trade/Device Name: ESA Biosciences LeadCare II Lead Control  
Regulation Number: 21 CFR 862.3280  
Regulation Name: Clinical Toxicology control material  
Regulatory Class: Class I, reserved  
Product Code: DIF  
Dated: November 8, 2006  
Received: November 9, 2006

Dear Mr. Byrd:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

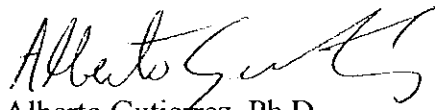
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2 –

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Alberto Gutierrez', with a stylized flourish at the end.

Alberto Gutierrez, Ph.D.

Director

Division of Chemistry and Toxicology

Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known):

K063398

Device Name: ESA Biosciences LeadCare II Control

### Indications For Use:

ESA Biosciences LeadCare II Control is intended to be used to monitor and evaluate the analytical performance of the ESA Biosciences LeadCare II Analyzer for the measurement of lead in blood. The use of quality control materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practice. The two levels of lead provided by the controls allow performance monitoring within the clinically important range.

### For *In Vitro* Diagnostic Use

Prescription Use √  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Page 1 of 1

Carol C Benson  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

K063398

14